



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 556, and 558

[Docket No. FDA-2017-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Changes of Sponsorship; Change of a Sponsor's Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during July, August, and September 2017. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect the withdrawal of approval of applications, changes of sponsorship of applications, and a change of a sponsor's name and address, and to make technical amendments to improve the accuracy of the regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], except for amendatory instructions 3 to 21 CFR 510.600, 9 to 21 CFR 522.300, 10 to 21 CFR 522.540, and 11 to 21 CFR 522.1081, which are effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July, August, and September 2017, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm>. Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: <https://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm>.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During July, August, and September 2017

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
July 21, 2017	141-450	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	BANAMINE Transdermal (flunixin transdermal solution) Solution	Cattle	Original approval for the control of pyrexia associated with bovine respiratory disease and the control of pain associated with foot rot in steers, beef heifers, beef cows, beef bulls intended for slaughter, and replacement dairy heifers under 20 months of age	FOI Summary; EA/FONSI ¹
July 19, 2017	141-336	ECO LLC, 344 Nassau St. Princeton, NJ 08540	AIVLOSIN (tylvalosin tartrate) Water Soluble Granules	Swine	Supplemental approval for control of swine respiratory disease (SRD) associated with <i>Bordetella bronchiseptica</i> , <i>Haemophilus parasuis</i> , <i>Pasteurella multocida</i> , and <i>Streptococcus suis</i> in groups of swine in buildings experiencing an outbreak of SRD	FOI Summary
July 14, 2017	200-620	Aurora Pharmaceutical, LLC, 1196 Highway 3 South Northfield, MN 55057-3009	ALTREN (altrenogest) Solution	Horses	Original approval as a generic copy of NADA 131-310	FOI Summary
July 14, 2017	200-621	Aurora Pharmaceutical, LLC, 1196 Highway 3 South Northfield, MN 55057-3009	SWINEMATE (altrenogest) Solution	Swine	Original approval as a generic copy of NADA 141-222	FOI Summary
September 15, 2017	141-250	Zoetis Inc. 333 Portage St. Kalamazoo, MI 49007	Chlortetracycline and lasalocid Type B and Type C medicated feeds	Cattle	Supplemental approval of revised representative labeling making technical amendments	
September 28, 2017	141-333	Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137	SENTINEL SPECTRUM (milbemycin oxime/ lufenuron/praziquantel)	Dogs	Supplemental approval for the treatment and control of the adult tapeworm <i>Dipylidium caninum</i>	FOI Summary

¹The Agency has carefully considered an environmental assessment (EA) of the potential environmental impact of this action and has made a finding of no significant impact (FONSI).

II. Change of Sponsorship

SmartVet USA, Inc., 22201 West Innovation Dr., suite 170A, Olathe, KS 66061-1304 has informed FDA that it has transferred ownership of, and all rights and interest in, the following application to Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215:

File No.	Product Name	21 CFR Section
200-348	ECOMECTIN (ivermectin) Topical Solution	524.1193

Following this withdrawal of approval, SmartVet USA, Inc. is no longer the sponsor of an approved application. Accordingly, it will be removed from the list of sponsors of approved applications in § 510.600(c) (21 CFR 510.600(c)).

Strategic Veterinary Pharmaceuticals, Inc., 100 NW. Airport Rd., St. Joseph, MO 64503 has informed FDA that it has transferred ownership of, and all rights and interest in, the following application to Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland:

File No.	Product Name	21 CFR Section
109-305	Oxytocin Injection	522.1680

The animal drug regulations are being amended to reflect these changes of sponsorship.

III. Withdrawals of Approval

The following sponsors requested that FDA withdraw approval of the NADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Sponsor	Product Name	21 CFR Section
047-055	Watson Laboratories, Inc., 311 Bonnie Circle, Corona, CA 92880	Chorionic Gonadotropin Powder for Injection	522.1081
104-606	Watson Laboratories, Inc., 311 Bonnie Circle, Corona, CA 92880	Dexamethasone Sodium Phosphate Injection	522.540
139-633	Wildlife Laboratories, Inc., 1230 W. Ash St., suite D, Windsor, CO 80550	WILDNIL (carfentanil citrate) Injection	522.300

Following this withdrawal of approval, Watson Laboratories, Inc. is no longer the sponsor of an approved application. Accordingly, it will be removed from the list of sponsors of approved applications in § 510.600(c).

Elsewhere in this issue of the *Federal Register*, FDA gave notice that approval of NADAs 047-055, 104-606, and 139-633, and all supplements and amendments thereto, is withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these actions.

IV. Technical Amendments

Western Chemical, Inc., 1269 Lattimore Rd., Ferndale, WA 98248 has informed FDA that it has changed its name and address to Syndel USA, 1441 W. Smith Rd., Ferndale, WA 98248. ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115 has informed FDA that it has changed its name to ADM Animal Nutrition, Inc. Accordingly, we are amending § 510.600(c) to reflect these changes.

We are also making technical amendments to update the scientific name of a pathogenic bacterium, to accurately list the concentrations of ingredients in a combination new animal drug, and to correctly list the assay limits and maximum drug concentration in Type B medicated feeds for a combination new animal drug used in feed. These actions are being taken to improve the accuracy of the regulations.

V. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C.360b(i)), which requires *Federal Register* publication of "notice[s]... effective as a regulation," of the conditions of use of approved new animal drugs. This rule sets

forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

Although denominated a rule pursuant to the FD&C Act, this document does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a "rule of particular applicability."

Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as "an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency."

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, and 524

Animal drugs.

21 CFR Part 556

Animal drugs, Food.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510, 520, 522, 524, 556, and 558 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. In § 510.600, in the table in paragraph (c)(1), remove the entries for "ADM Alliance Nutrition, Inc.", "SmartVet USA, Inc." and "Western Chemical, Inc.", and add entries for "ADM Animal Nutrition, Inc." and "Syndel USA" in alphabetical order; and in the table in paragraph (c)(2), remove the entry for "086001" and revise the entries for "012286" and "050378" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
ADM Animal Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115	012286
* * * * *	
Syndel USA, 1441 W. Smith Rd., Ferndale, WA 98248	050378
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
012286	ADM Animal Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115
* * * * *	
050378	Syndel USA, 1441 W. Smith Rd., Ferndale, WA 98248
* * * * *	

3. Effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], in § 510.600, in the table in paragraph (c)(1), remove the entry for "Watson Laboratories, Inc."; and in the table in paragraph (c)(2), remove the entry for "000402".

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

4. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.48 [Amended]

5. In § 520.48, in paragraph (b), remove "000061 and 061623" and in its place add "000061, 051072, and 061623".

§ 520.1447 [Amended]

6. In § 520.1447, in paragraph (d)(1)(ii), remove "*Taenia pisiformis*, *Echinococcus multilocularis*, and *E. granulosus*" and in its place add "*Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus multilocularis*, and *E. granulosus*".

7. In § 520.2645, revise paragraphs (d)(1) and (2) to read as follows:

§ 520.2645 Tylvalosin.

* * * * *

(d) * * *

(1) *Amount*. Administer 50 parts per million (ppm) tylvalosin continuously in drinking water for 5 consecutive days.

(2) *Indications for use*. For control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine in buildings experiencing an outbreak of PPE; and for control of swine respiratory disease (SRD) associated with *Bordetella*

bronchiseptica, *Haemophilus parasuis*, *Pasteurella multocida*, and *Streptococcus suis* in groups of swine in buildings experiencing an outbreak of SRD.

* * * * *

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

8. The authority citation for part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.300 [Removed]

9. Effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], remove § 522.300.

10. Effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], in § 522.540, revise paragraphs (b)(2) and (c)(2) to read as follows:

§ 522.540 Dexamethasone solution.

* * * * *

(b) * * *

(2) *Sponsor*. See No. 061623 in § 510.600(c) of this chapter.

* * * * *

(c) * * *

(2) *Sponsor*. See No. 061623 in § 510.600(c) of this chapter.

* * * * *

§ 522.1081 [Amended]

11. Effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], in § 522.1081, in paragraph (b)(1), remove "Nos. 000402 and 054771" and in its place add "No. 054771".

§ 522.1662a [Amended]

12. In § 522.1662a, in paragraph (h)(3)(ii), remove "*Spherophorus necrophorus*" and in its place add "*Fusobacterium necrophorum*".

§ 522.1680 [Amended]

13. In § 522.1680, in paragraph (b), remove "054628,".

PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

14. The authority citation for part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

15. Add § 524.970 to read as follows:

§ 524.970 Flunixin.

(a) *Specifications*. Each milliliter of solution contains 50 milligrams (mg) flunixin (equivalent to 83 mg flunixin meglumine).

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.286 of this chapter.

(d) *Conditions of use*--(1) *Amount*. Apply only once at a dose of 3.3 mg flunixin per kg body weight (1.5 mg/lb; 3 mL per 100 lbs) topically in a narrow strip along the dorsal midline from the withers to the tailhead.

(2) *Indications for use*. For the control of pyrexia associated with bovine respiratory disease and the control of pain associated with foot rot in steers, beef heifers, beef cows, beef bulls intended for slaughter, and replacement dairy heifers under 20 months of age.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Cattle must not be slaughtered for human consumption within 8 days of the last treatment. Not for use in female dairy cattle 20 months of age or older, including dry dairy

cows; use in these cattle may cause drug residues in milk and/or in calves born to these cows or heifers. Not for use in suckling beef calves, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

16. In § 524.1132, revise paragraph (a) to read as follows:

§ 524.1132 Hydrocortisone, miconazole, and gentamicin otic suspension.

(a) *Specifications*. Each milliliter (mL) of suspension contains 1.11 milligrams (mg) hydrocortisone aceponate, 17.4 mg miconazole nitrate, and 1.5 mg gentamicin (as gentamicin sulfate).

* * * * *

§ 524.1193 [Amended]

17. In § 524.1193, in paragraph (b)(2), remove "086001" and in its place add "058005".

PART 556--TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

18. The authority citation for part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

§ 556.286 [Amended]

19. In § 556.286, in paragraph (c), remove "§§ 522.956 and 522.970" and in its place add "§§ 522.956, 522.970, and 524.970".

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

20. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

21. In § 558.4, in paragraph (d), in the "Category II" table, revise the row entries for "Neomycin" through "Pyrantel tartrate" to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

CATEGORY II

Drug	Assay limits percent ¹ Type A ¹	Type B maximum (100x)	Assay limits percent ¹ Type B/C ²
* * * * *			
Neomycin.....	80-120	20 g/lb (4.4%)	70-125.
Oxytetracycline.....	80-120	20 g/lb (4.4%)	65-135.
Neomycin sulfate.....	80-120	100 g/lb (22.0%).....	70-125.
Nicarbazin (granular).....	90-110	5.675 g/lb (1.25%).....	85-115/75-125.
Narasin.....	90-110	5.675 g/lb (1.25%).....	85-115/75-125.
Nicarbazin (powder).....	98-106	5.675 g/lb (1.25%).....	85-115/80-120.
Novobiocin.....	85-115	17.5 g/lb (3.85%).....	80-120.
Pyrantel tartrate.....	90-110	36 g/lb (7.9%).....	75-125.
* * * * *			

¹Percent of labeled amount.

²Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

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22. In § 558.128, revise paragraphs (e)(3)(vi), (e)(4)(ix), and (e)(4)(xxvi) to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(3) * * *

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * * *				
(vi) 10 mg/lb of body weight	Tiamulin hydrogen fumarate, 35	For control of swine dysentery associated with <i>Brachyspira</i> (formerly <i>Serpulina</i> or	Feed chlortetracycline at approximately 400 g/ton of feed, varying with body weight and food consumption, to provide	058198 069254

		<i>Treponema hyodysenteriae</i> susceptible to tiamulin and for treatment of swine bacterial enteritis caused by <i>E. coli</i> and <i>Salmonella choleraesuis</i> sensitive to chlortetracycline and treatment of bacterial pneumonia caused by <i>P. multocida</i> sensitive to chlortetracycline	10 mg/lb of body weight. Feed continuously as the sole ration for 14 days. Withdraw medicated feed 2 days before slaughter. Tiamulin as provided by Nos. 058198 or 069254 in § 510.600(c) of this chapter	
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(4) * * *

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * * *				
(ix) 500 to 4,000 to provide 10 mg/lb of body weight daily	Lasalocid, 30 to 600	Pasture cattle (slaughter, stocker, feeder cattle, dairy and beef replacement heifers): For treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline; and for increased rate of weight gain	Feed continuously on a hand-fed basis for not more than 5 days to provide 10 mg chlortetracycline per lb. body weight per day and not less than 60 mg or more than 300 mg lasalocid per head per day in at least 1 pound of feed. Daily lasalocid intakes in excess of 200 mg/head/day in pasture cattle have not been shown to be more effective than 200 mg lasalocid/head/day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter	054771
* * * * *				
(xxvi) 500 to 4,000 to provide 10 mg/head/day	Lasalocid, 30 to 181.8	Cattle weighing up to 800 pounds: For the treatment of bacterial enteritis caused by	Hand feed continuously for not more than 5 days at a rate of 10 mg chlortetracycline and 1 mg lasalocid per 2.2 lb. body weight	054771

		<i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> susceptible to chlortetracycline; and for the control of coccidiosis caused by <u><i>Eimeria bovis</i></u> and <u><i>E. zuernii</i></u>	daily to cattle with a maximum of 360 mg of lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter	
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23. In § 558.325, revise paragraph (d)(2) to read as follows:

§ 558.325 Lincomycin.

* * * * *

(d) * * *

(2) The expiration date of VFDs for lincomycin medicated feeds must not exceed 6 months from the date of issuance. VFDs for lincomycin shall not be refilled.

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§ 558.575 [Amended]

24. In § 558.575, in paragraph (e)(2)(ii) remove "and bacterial infections due to *H. galmaxima*".

Dated: March 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-06358 Filed: 3/29/2018 8:45 am; Publication Date: 3/30/2018]